Unapproved Drugs Coordinator Role

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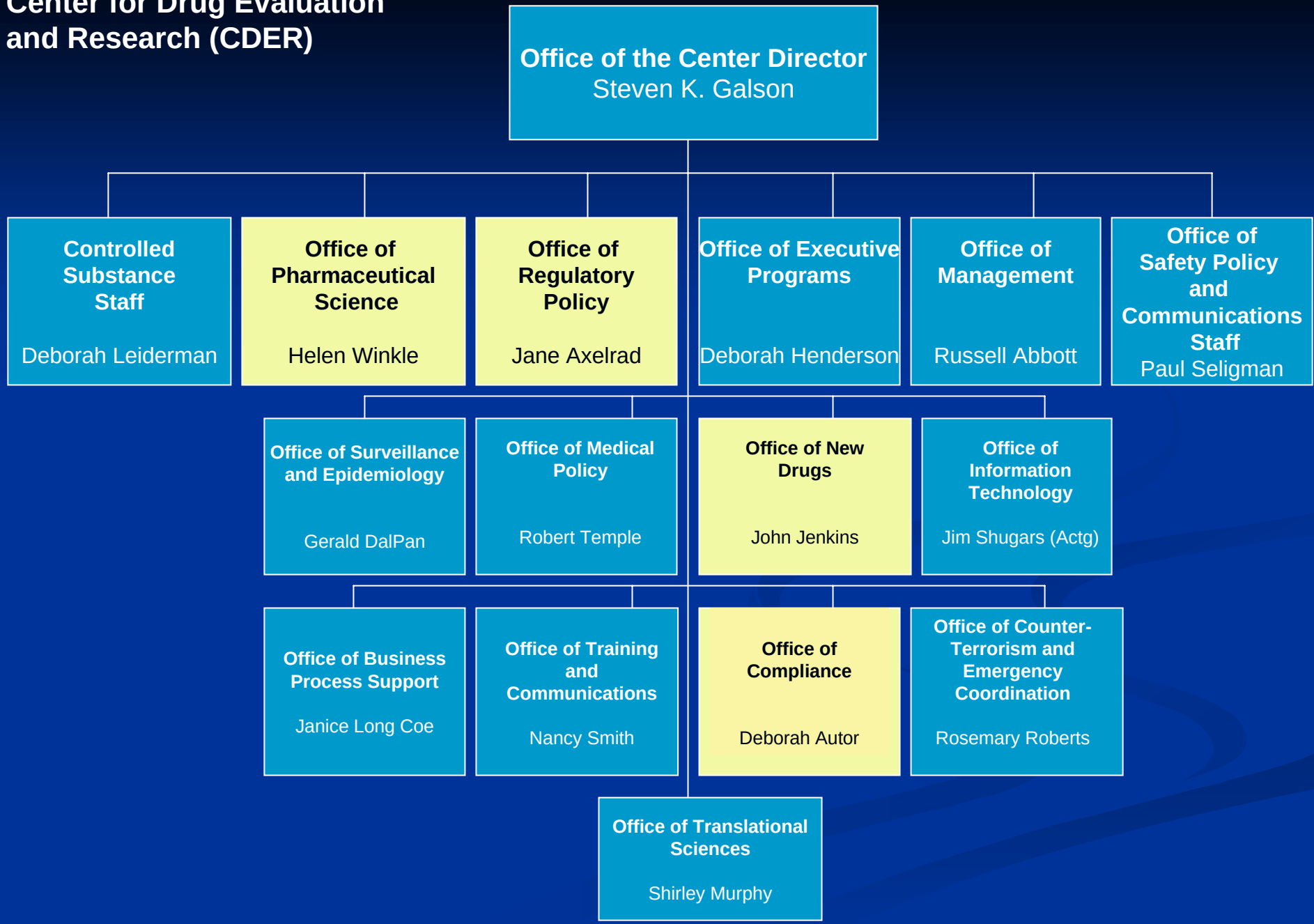
Center for Drug Evaluation and Research (CDER)

Unapproved Drugs coordinator

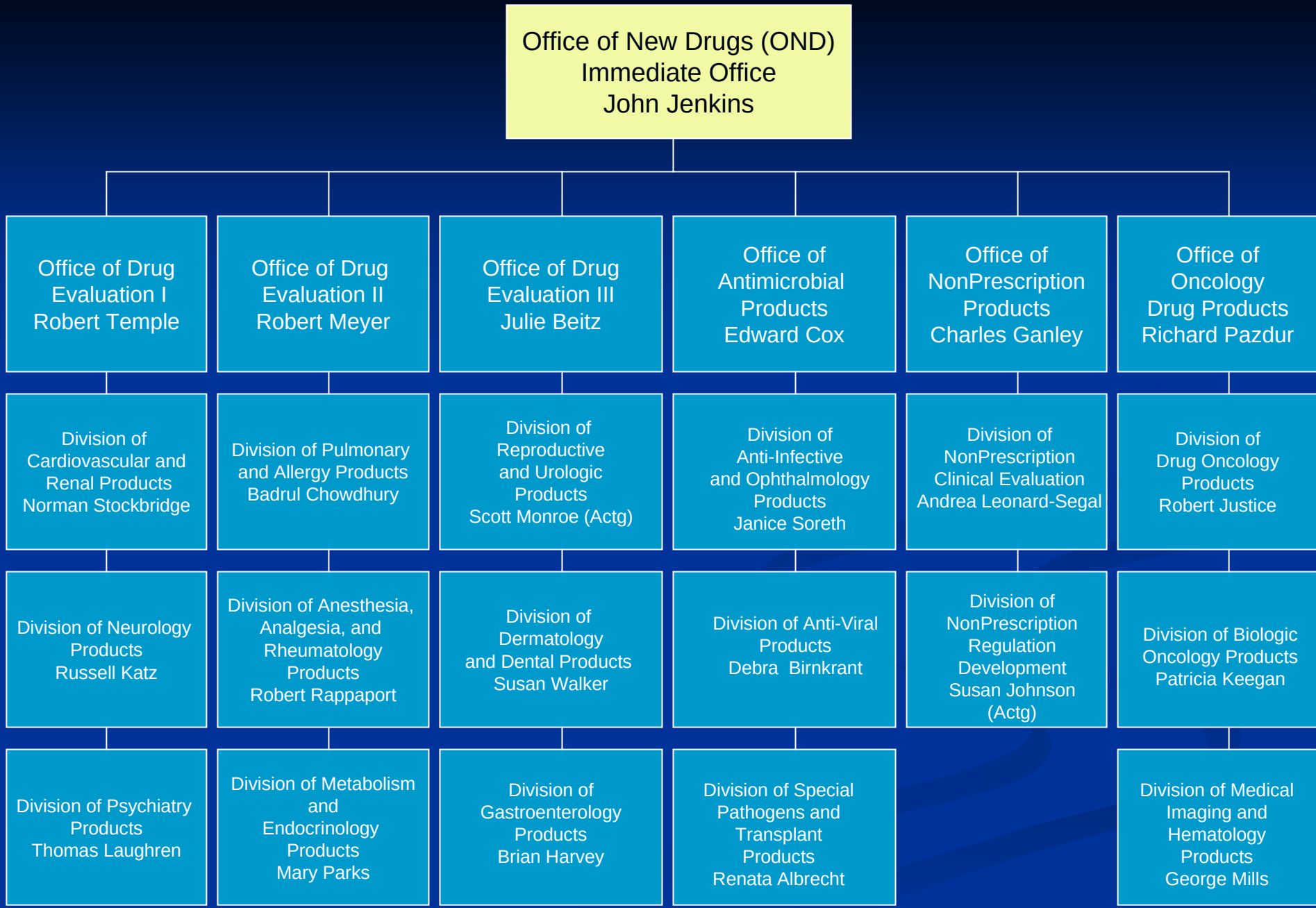
- Arose out of external inquiry about the potential inconsistencies in the application of review standards among Divisions within Office of New Drugs (OND) for marketed unapproved drugs
- Officially established in Dec. 2005
- Point of Contact for Center and OND

Center for Drug Evaluation and Research (CDER)



Duties

- **Center Level**
  - Act as a point of contact for Sponsors interested in pursuing an application
    - Provide contacts for appropriate Offices
      - Office of New Drugs
      - Office of Pharmaceutical Science
        - Office of Generics
      - Office of Regulatory Policy
        - User Fee Staff
      - Office of Compliance
        - Member of Compliance-led cross Agency unapproved drugs working group


Office of New Drugs (OND)
Immediate Office
John Jenkins
Office of Drug Evaluation I
Robert Temple
Office of Drug Evaluation II
Robert Meyer
Office of Drug Evaluation III
Julie Beitz
Office of Antimicrobial Products
Edward Cox
Office of NonPrescription Products
Charles Ganley
Office of Oncology Drug Products
Richard Pazdur
Division of Cardiovascular and Renal Products
Norman Stockbridge
Division of Pulmonary and Allergy Products
Badrul Chowdhury
Division of Reproductive and Urologic Products
Scott Monroe (Actg)
Division of Anti-Infective and Ophthalmology Products
Janice Soreth
Division of NonPrescription Clinical Evaluation
Andrea Leonard-Segal
Division of Drug Oncology Products
Robert Justice
Division of Neurology Products
Russell Katz
Division of Anesthesia, Analgesia, and Rheumatology Products
Robert Rappaport
Division of Dermatology and Dental Products
Susan Walker
Division of Anti-Viral Products
Debra Birnkrant
Division of NonPrescription Regulation Development
Susan Johnson (Actg)
Division of Biologic Oncology Products
Patricia Keegan
Division of Psychiatry Products
Thomas Laughren
Division of Metabolism and Endocrinology Products
Mary Parks
Division of Gastroenterology Products
Brian Harvey
Division of Special Pathogens and Transplant Products
Renata Albrecht
Division of Medical Imaging and Hematology Products
George Mills

Duties

- **OND Level**
  - Act as a point of contact for Sponsors interested in pursuing an application
  - Discuss general approach to getting started
    - Reviewing and summarizing the literature and any existing primary data
    - Requesting a pre-IND meeting with the appropriate OND Division
    - Providing contacts for appropriate OND review Divisions
  - Act as a liaison to the review Divisions to aid in consistency of OND's handling and response to requests for approval of marketed unapproved drugs
    - Interact with Divisions during the pre-meeting to help facilitate responses and identify any policy issues that may arise
    - Provide feedback and direction based on experiences in other Divisions
    - Update Divisions on related compliance actions

Industry Experiences

- Industry inquiries:
  - Where to start?
  - Who to submit to?
  - What studies are needed?
  - Do I have to pay User fees?
  - Clinical trial requirements?
  - Compliance guidance questions
    - Enforcement Discretion questions

OND Experience

- Briefing held or planned for
  - OND Office management
  - OND Division management
  - OND Reviewers
- Goal
  - Raise awareness
  - Raise and address policy issues
  - Standardize our approach across all Divisions

Workshop

- This workshop originated from the inquires received by the Office of New Drugs and the Office of Compliance
  - It was modeled after the type of frequently asked questions received
  - Intent was to give a broad look at the application process knowing that many Sponsors of unapproved drugs are small businesses with limited knowledge of the regulatory process
  - It is understood that each Sponsor will have different issues related to their drug product and those scientific issues should be directed to the relevant OND Division

Getting Started

- Review Guidances
- Review Literature
- Request a Pre-IND Meeting
- Meeting Package should include: 505(b)(2)
  - Review of the literature and a summary of the articles that are considered relevant to your application
    - Pharmacology/Toxicology
    - Clinical Pharmacology
    - Clinical Efficacy
    - Clinical Safety
  - Proposed Indication
  - Dose and Dosage form
  - Chemistry, Manufacturing. & Controls
    - Sufficient info to assure identity, strength, quality and purity

Contact Information

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